I. AMENDMENT

In the Claims:

Please cancel claims 5, 6, 8, 9, 31, 32, 36 and 37 without prejudice or disclaimer. Please amend claims 1, 3, 4, 10, 30, 33 and 33-35 as indicated below:

1. (Amended) A method of treating diabetes comprising administering to an animal having diabetes an active compound from a berry from a plant of the Panax genus, wherein the active compound comprises ginsenoside Re.

3. (Amended) The method of claim 2, wherein the active compound comprises an anti-hyperglycemic compound.

4. (Amended) The method of claim 3, wherein the active compound comprises purified ginsenoside Re.

10. (Amended) The method of claim 3, wherein the active compound comprises an anti-obesity compound.

30. (Amended) A method of treating an animal having hyperglycemia comprising administering to the animal an active compound from a berry from a plant of the Panax genus, wherein the active compound comprises ginsenoside Re.

33. (Amended) The method of claim 30, wherein the active compound comprises an anti-obesity compound.

34. (Amended) A method of treating an animal to decrease blood glucose levels comprising administering to the animal an active compound from a berry from a plant of the Panax genus, wherein the active compound comprises ginsenoside Re.

35. (Amended) The method of claim 34, wherein the active compound comprises an anti-hyperglycemic compound.

~~38. (Amended) The method of claim 35, wherein the active compound comprises an anti-~~ obesity compound.

Please add new claims 52-74 as follows:

52. (New) The method of claim 30, wherein the active compound comprises purified ginsenoside Re.

53. (New) The method of claim 35, wherein the active compound comprises purified ginsenoside Re.

54. (New) A method of treating diabetes comprising administering to an animal having diabetes an active compound from a berry from a plant of the Panax genus, wherein the plant is *Panax quinquefolius*.

55. (New) The method of claim 54, wherein the active compound comprises an anti-hyperglycemic compound.

56. (New) The method of claim 55, wherein the active compound comprises a ginsenoside.

57. (New) The method of claim 55, wherein the active compound comprises at least two ginsenosides.

58. (New) The method of claim 55, wherein the active compound comprises non-ginsenoside components of berry extract.

59. (New) The method of claim 55, wherein the active compound is ginsenoside free.

60. (New) The method of claim 55, wherein the active compound comprises an anti-obesity compound.

61. (New) The method of claim 54, wherein the animal has non-insulin dependent diabetes.

62. (New) The method of claim 54, wherein the animal is a mammal.

63. (New) The method of claim 62, wherein the mammal is a human.

64. (New) The method of claim 63, wherein the human is obese.

65. (New) A method of treating an animal having hyperglycemia comprising administering to the animal an active compound from a berry from a plant of the Panax genus, wherein the plant is *Panax quinquefolius*.

66. (New) The method of claim 65, wherein the active compound comprises a ginsenoside.

67. (New) The method of claim 66, wherein the ginsenoside is Re.

68. (New) The method of claim 65, wherein the active compound comprises an anti-obesity compound.

69. (New) A method of treating an animal to decrease blood glucose levels comprising administering to the animal an active compound from a berry from a plant of the Panax genus, wherein the plant is *Panax quinquefolius*.

70. (New) The method of claim 69, wherein the active compound comprises an anti-hyperglycemic compound.

71. (New) The method of claim 70, wherein the active compound comprises a ginsenoside.

72. (New) The method of claim 71, wherein the ginsenoside is Re.

73. (New) The method of claim 70, wherein the active compound comprises an anti-obesity compound.

74. (New) The method of claim 56, wherein the active compound further comprises a non-ginsenoside component.

II. REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. §1.111

A. Status of the Claims

Claims 1-22, 30-38 and 51 were pending at the time of the Action and correspond to Group I identified in the previous Restriction Requirement. Claims 1, 3, 4, 10, 30, and 33-35 were amended herein. Claims 5, 6, 8, 9, 31, 32, 36 and 37 have been canceled and claims 52-74 added. The new claims are all within the scope of the originally pending claims of Group I. Support for the claims is found in the claims as filed. Additional support for purified ginsenoside Re is found, at least, from page 36, line 26 to page 37, line 2 and additional support for "compound" is found, at least, at page 41, lines 19-22. No new matter is added by the amendments. Claims 1-7, 10-22, 30-38 and 51-72 are now pending and are presented herein or reconsideration. The Commissioner is authorized to deduct any additional claim fees from the deposit account of Applicants' representative as set forth above.

B. Objection to the Information Disclosure Statement

The Action objects to the Information Disclosure Statement filed 2/12/2002, on page 4, as not complying with 37 CFR § 1.98(a)(3). In response, Applicants note that a translation of the reference from Russian to English is currently being prepared. The translation will be provided promptly after it has been prepared. In light of the foregoing, Applicants respectfully request removal of the objection.

C. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects claims 3, 10, 33, 35 and 38 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which Applicant regards

as the invention. In particular, the Action asserts that the phrases "antihyperglycemic constituent" and "anti-obesity constituent" render the claims indefinite because it is not known what "constituent" refers to.

In response, Applicants note that "constituent" has been amended in the subject claims to "compound." The amendments do not narrow the claims and therefore Applicants do not intend to disclaim any subject matter through the amendment. In view of the amendment, the rejection is now believed to be moot and removal thereof is thus respectfully requested.

D. Rejection Under 35 U.S.C. §102(b)

The Action rejects claims 1-7, 10, 17-19, 30-38 and 51 under 35 U.S.C. §102(b) as anticipated by JP 07267977A (English abstract), with evidence provided by Gruenwald, J. *et al.*, (eds.) (PDR for Herbal Medicines. 1998. Medical Economics Co., Montvale, N.J., Pg 1009). In particular, it is stated that JP 07267977A teaches administration of a glycoside from *Panax ginseng* as a health food for treating diabetes.

In response, Applicants first note that the claims have been amended to specify that the active compound administered is ginsenoside Re. None of the references teach or suggest the use of ginsenoside Re for treating diabetes, hyperglycemia or for decreasing blood glucose levels. The position in the Action is that Gruenwald *et al.* teaches that ginseng extract comprises a number of components, and shows that JP 07267977A inherently uses the individual compounds listed in Gruenwald *et al.* However, Applicants first note that Gruenwald *et al.* indicates that the medicinal part of the plant is the roots, not a berry. Thus the discussion of *Panax ginseng* components appears to be made with respect to the roots. Further, the instant

claims are limited to use of ginsenoside Re. No demonstration has been made that JP 07267977A contemplates use of ginsenoside Re.

Gruenwald lists ginseng as having more than 20 ingredients. The reference further is silent as to whether any one or more of these ingredients is present in the fruit of *Panax ginseng*, as only the roots are indicated to be the medicinal part of the plant. No basis has therefore been provided to indicate that any one given component is inherent in any extract contemplated for use by JP 07267977A, or that a given component would have activity allegedly taught by the reference. Under the law of inherency, it must be shown that the claimed use of ginsenoside Re necessarily flows from the cited reference. That is, anticipation requires that each and every element of the claimed invention be described, either expressly or inherently, in a single prior art reference. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001). Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1994). Moreover, the Federal Circuit has repeatedly stated that "the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Telemac Cellular*, 247 F.3d at 1328; *Continental Can*, 948 F.3d at 1268 (Fed. Cir. 1994). In fact, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *In re Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Interferences 1990) (citing *In re King*, 231 U.S.P.Q. 136 (Fed. Cir. 1986)); *See also Ex Parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (Bd. Pat. App. & Interferences 1986).

The only evidence alleged in support of inherency is the mention of ginseng extracts in JP 07267977A and a description in Gruenwald *et al.* of a laundry list of components contained in *Panax ginseng*. However, as indicated above, Gruenwald *et al.* indicates that the medicinal part of the plant is the roots, whereas JP 07267977A refers to a "fruit extract." Gruenwald *et al.* therefore refers to a *different* ginseng extract and cannot be used in support of inherency. No factual basis has been presented to indicate that the components in a root extract are the same as a fruit extract. As such, ginsenoside Re or any activity therefore does not necessarily flow from the prior art and the claims are not anticipated.

With regard to claims 4, 52 and 53, it is further noted that these claims specify that the active compound is purified ginsenoside Re. In contrast, JP 07267977A deals only with extracts, not purified ginsenoside, let alone ginsenoside Re. The reference therefore does not anticipate claims 4, 52 and 53 for this additional reason as well.

With respect to new claims 52-72, it is noted that these claims specify administering an active compound from a berry of a *Panax quinquefolius* plant. None of the cited references teach use of active compounds from *Panax quinquefolius* in general, and particularly for the claimed methods. Both of JP 07267977A and Gruenwald *et al.* concern *Panax ginseng* and not *Panax quinquefolius*. While Gruenwald *et al.* mentions the existence of *Panax quinquefolius*, the reference indicates that it is *Panax ginseng* that is being referred to and no indication of any components of *Panax quinquefolius* are given. This element of the claims is thus lacking from the prior art. Applicants therefore respectfully request the removal of the rejection under 35 U.S.C. §103.

E. Rejections Under 35 U.S.C. §103(a)

The Action rejects claims 1-7, 10-14, 17-22, 30-38 and 51 under 35 U.S.C. §103(a) as being obvious over JP 07267977A (English abstract) in view of Yegorova *et al.* (U.S. Patent No. 6,399,089). In particular, it is stated that JP 07267977A teaches compositions from ginseng berries, but not methods of treating obesity. It is stated that Yegorova *et al.* teach a method of treating diabetes and obesity comprising administration of *Panax ginseng* to humans. It is further stated that one of skill in the art would have been motivated to combine the references for treatment of diabetes or obesity using ginseng extracts.

In response, Applicants first note that the claims have been amended to specify that the active compound administered is ginsenoside Re. Neither of the cited reference teach or suggest the use of ginsenoside Re for treating diabetes, hyperglycemia or for decreasing blood glucose levels. Yegorova refers generally to "*Panax ginseng* extract" and fails to mention any specifics about the extract or any ingredients therein. Further, the *Panax ginseng* extract is mentioned as only one of the components in the active compositions, which also include chromium, fat-free cocoa powder, *Hypericum perforatum* extract, *Gercinia cambogia* extract, *Gingko biloba* extract and quercetin. Once again, one would be completely without guidance as to whether any single ingredient and particularly whether any given ingredient, and particularly any specific ginsenoside, would have activity.

The shortcomings of the prior art are underscored by JP 07267977A. This reference lists diabetes mellitus as one of many potential uses, including: (1) loss of mental power an vitality caused by aging, (2) blood vessel diseases in the heart and brain, (3) arteriosclerosis and hyperlipaemia (sic), (4) hypoplastic anemia; (5) hypoplasia in infants, (6) nocturnal enuresis and climatic difficulties, (7) depilation, and (8) increase of body temp. The inclusion of diabetes in

this laundry list does nothing to inform the art whether any active ingredient has a particular activity and, specifically, whether any specific ginsenoside is present or has biological activity. No teaching with respect to ginsenoside Re can thus be derived from the reference.

With regard to claims 4, 52 and 53, it is further noted that these claims specify that the active compound is purified ginsenoside Re. Neither cited reference teaches or suggests use of purified ginsenoside, not to mention ginsenoside Re. This element is therefore completely absent from the cited references, and therefore the claims may not be rejected under 35 U.S.C. §103. One of skill in the art was further completely without guidance as to whether purified ginsenoside Re has biological activity for the treatment of diabetes and hyperglycemia or for decreasing blood glucose. These claims are therefore non-obvious for this additional reason as well.

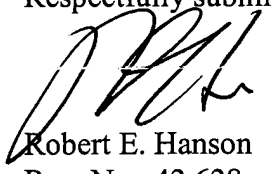
With respect to new claims 52-72, it is again noted that these claims specify administering an active compound from a berry of a *Panax quinquefolius* plant. None of the cited references teach use of active compounds from *Panax quinquefolius* in general, or particularly for the claimed methods. All of the elements of the claims have therefore not been disclosed in the prior art, as required to support a rejection under 35 U.S.C. §103.

In view of the foregoing, removal of the rejection under 35 U.S.C. §103 is respectfully requested.

F. Conclusion

In light of the foregoing, applicants submit that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. The examiner is invited to contact the undersigned (512)536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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